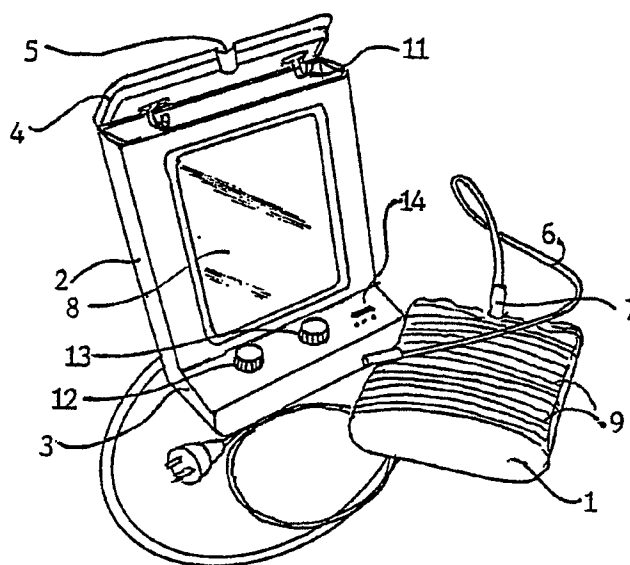




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(54) Title: SUCTION SYSTEM FOR WOUND AND GASTRO-INTESTINAL DRAINAGE



(57) Abstract

A hollow chamber (2) adapted to receive a collapsible reservoir (1) for the collection of body fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means (4) to close and seal said reservoir such that a vacuum may be generated and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means (8) to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port (5) to facilitate a liquid conduit passing into the chamber.

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SUCTION SYSTEM FOR WOUND AND GASTRO-INTESTINAL DRAINAGE

The present invention relates to drainage of wounds and in particular to a system incorporating a suction device to facilitate such drainage.

5 The parting of flesh and bone occasioned by surgical intrusions into the body result in the secretion of low volumes of fluid into the wound even when the wound is correctly sutured or stabilised by other means in order to facilitate rapid healing. These fluids inhibit effective healing and consequently it has been the practice
10 for many years to drain such fluids from the body during the healing process.

 Such drainage is achieved by the introduction of a perforated cannula into the area of the wound, the cannula remaining in the wound and exiting through the skin to facilitate drainage for a
15 number of days after closing of the wound.

 In order to assist drainage of the wound a mild vacuum has been found desirable.

 Traditionally the cannula is placed in communication with a vacuum via a tube which tube is also in communication with a
20 reservoir for collection of drained fluid. There are presently two drainage systems in widespread use; the first utilising a disposable or re-usable bottle into which a vacuum is drawn. This bottle is then connected directly to the wound site by means of a length of plastic tubing terminating in the perforated cannula within the
25 wound. This system however suffers from the disadvantage that a constant vacuum is not applied to the wound area. When the bottle

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is initially placed in communication with the wound an adequate pre-determined vacuum is available in order to ensure drainage although as fluid drains into the bottle and after the bottle is exposed to the wound for some time period the available vacuum naturally decreases. International standards specify that it is not desirable to expose wounds to vacuums exceeding 180 millimetres of mercury (negative pressure) although in order to evacuate a bottle fully so that it will fill to capacity.

a much higher vacuum needs to be applied. Given that this starting vacuum is two or often three times that considered safe and acceptable displacement of vacuum by entering fluid means that the vacuum will slowly diminish through a safe level, then down to an unacceptable low level.

In order to prevent mucosa or tissue adhering to the perforated cannula and thereby impeding flow it is additionally desirable to provide an intermittent vacuum and it is difficult to achieve such result with the lastmentioned pre-charged bottle system.

The second system currently utilised involves an electrically operated pump capable of generating a vacuum and connected to the wound site via a collection jar or jars. This lastmentioned system can readily be programmed to provide an intermittent vacuum thus preventing mucosa or tissue adhering to the perforated cannula and allowing pooling of fluids in the wound site during the off-cycle ready for evacuation during the next on-cycle. Electrical suction units as lastmentioned however require the installation of

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a bottle between the suction unit and the cannula and the changing of such bottle when filled. As patients may be suffering from communicable diseases such as AIDS the handling and changing of bottles by nursing staff is undesirable as the staff may come into
5 contact with the evacuated fluids.

The present invention seeks to ameliorate one or more of the abovementioned disadvantages with existing suction systems or at least provide the consumer with an alternative system for wound drainage.

10 According to the present invention there is provided a hollow chamber adapted to receive a collapsible reservoir for the collection of fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means to close and seal said reservoir such that a vacuum may be generated
15 and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port to facilitate a liquid conduit passing into the chamber.

20 One embodiment of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a perspective view of the principal components of a system in accordance with the present invention; and Figure 2 is a frontal view from the top of an assembled system in accordance with the present invention.

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Figure 1 depicts a collapsible plastic reservoir 1 and a moulded chamber 2. The moulded chamber includes a vacuum pump (not shown) in its base 3 and is provided with a hinged lid 4 to facilitate loading the chamber with the collapsible reservoir 1. The lid incorporates a seal along its interface with the main body of the chamber such that when the lid is in a closed state a vacuum may be induced in the chamber 2. It will be noted that the lid 4 is notched at 5 in order to accommodate the plastic tube 6 and cannula connecting the reservoir to the wound site. It will be noted that the plastic tubing terminates in an enlarged joining piece 7 before it enters the reservoir, this enlarged joining piece serving a dual function. Firstly the enlarged joining piece, in this case of silicon, is resiliently deformable so as to conform to the shape of notch 5 thereby ensuring a good seal where the joining piece passes through the lid 4. The silicon joining piece additionally facilitates penetration by a needle and syringe in order that sampling or testing of fluids entering the reservoir may occur.

It will be noted that the chamber 2 has a transparent face portion 8 in order that the level in the reservoir may be observed without disturbing the system. It may further be observed that the reservoir itself is transparent and is provided with marked graduations 9 in order that the volume of fluid in the reservoir may be readily determined.

As may best be observed from figure 2 the upper portion of the welded borders of the reservoir are provided with apertures 10

intended to co-operate with hooks 11 on the underside of the lid 4 of the chamber 2 in order that the reservoir may be adequately supported within the chamber 2.

An alternate system not depicted would be to utilise press studs say male press studs on the inside of the chamber with female press studs on the external surface of the reservoir. If metal press studs were utilised then this system could be worked in with a "reservoir full" sensor. For example the press studs on the reservoir could be in electrical communication with short metal tapes extending down the inside of the bag. When the bag became full of liquid then the electrical resistance between each of the two said metal tapes would change thus enabling a sensor unit in the chamber and communicating with the reservoir through the press studs to determine the reservoir full state.

The vacuum pump (not shown) in the base 3 communicates with the chamber 2 via an inlet (not shown) adjacent the upper portion of the chamber. With such an inlet should a reservoir ever rupture fluid will not readily enter the pump unit. The base of the chamber preferably incorporates a moisture sensor which operates an alarm and pump cut off should a malfunction such as a rupture cause fluid to come into direct contact with the chamber. Control knobs 12 and 13 may be utilised to control the pump by selection of on/off or intermittent modes as well as regulating the vacuum. A bar graph 14 is provided in order that the level of vacuum may be accurately monitored. The L.E.D. depicted beneath the bar graph at 15 alert the operator as to specific faults or modes of the machine.

In this example three L.E.D.'s are provided the first being interconnected with a moisture sensor as above described in order

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to protect against any leakage.

The second L.E.D. indicates that status of a switching device which turns the unit off when the reservoir reaches a full state. This switching device may take the form of a magnet
5 implanted in the rear of the reservoir towards the top thereof which co-operates with a switching unit in the rear of the chamber when the reservoir is full and in an expanded state. The third sensor may warn as to a vacuum leakage as may occur when the wrong type of bag or no bag at all is inserted in the
10 chamber. When any of the three lastmentioned L.E.D.'s illuminate an audible alarm may also be activated and the pump unit is switched off.

It is not essential for the present invention that the vacuum pump receive power from the mains and indeed it may be
15 desirable in many circumstances that a battery back up be provided to ensure that the units operation was not dependent upon mains supply. In remote areas where access to mains power may be difficult and additionally in mobile applications such as ambulances and planes the unit could additionally be
20 designed so as to operate from a battery or vehicles electrical system.

It should be appreciated that the present system eliminates any contact between drained fluid and the chamber 2 and associated pump and control equipment. The reservoir, canulae and
25 plastic tubing may be disposed or removed to another location when full, again without the necessity of nursing staff coming into contact with fluid within the reservoir. The reservoir may

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for example be connected to the patient (say in an operating theatre) prior to insertion into a vacuum chamber thus facilitating easy transport of the patient and reservoir (with cannula implanted in the patient) back to a ward having a
5 suitable vacuum chamber.

Although the collapsible plastic reservoir is normally a sealed unit open only to the plastic tubing and cannula the chamber and vacuum unit should also be capable of accommodating a vented reservoir necessary to drain gastro intestinal wounds.
10 Where gastro intestinal wounds are being drained a volume of gas may be discharged into the cannula along with fluids and consequently this gas needs to be evacuated from the reservoir in order that the reservoir may fill with fluid. This reservoir consequently requires a vent in order that the gases may pass into
15 the chamber through the vacuum pump to atmosphere. A filter is required at the reservoir vent in such an embodiment.

It is desirable that all reservoirs should contain a non-return valve in order to prevent fluid returning along the inlet tubing and coming into contact with staff after the cannula
20 or reservoir is removed.

Although the above described embodiment contains an integral vacuum pump it should be appreciated that this is not essential to the present invention and that the entire vacuum chamber assembly with sensors etc. may usefully be provided without
25 a vacuum pump and adapted to plug into a central vacuum system usually present in modern hospitals.

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It should be appreciated that further embodiments apart from that above described may be devised without departing from the scope and intendment of the present invention.

DATED this 30th day of January, 1987.

ROGER L.W. OSMOND

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The claims defining the invention are as follows:

1. A hollow chamber adapted to receive a collapsible reservoir for the collection of fluids; an opening in said hollow chamber to facilitate the introduction and removal of a collapsible reservoir; means to close and seal said reservoir such that a vacuum may be generated and maintained in said chamber; a first port in said chamber to facilitate evacuation thereof; means to determine when a collapsible reservoir in the chamber is approaching a full state, and a second port to facilitate a liquid conduit passing into the chamber.
2. A chamber in accordance with claim 1 wherein the means to determine when a collapsible reservoir inside the chamber is approaching in full state is a transparent panel which allows observation of any collapsible reservoir within the chamber.
3. A chamber in accordance with any one of the preceding claims wherein there are additionally provided integrally with the chamber structure means for evacuating such chamber.
4. A chamber in accordance with claim 3 hereof wherein the integral evacuation mechanism is provided with a sensor and a variable control such that a range of pre-determined vacuums may be selected.
5. A chamber in accordance with any one of the preceding claims wherein the first (evacuation) port is located

adjacent an upper extremity of the chamber.

6. A chamber in accordance with any one of the preceding claims wherein the chamber includes adjacent a lower extremity a moisture sensor adapted to sense rupture of any reservoir within the chamber.
7. A chamber in accordance with any one of the preceding claims including a reservoir full sensor adapted to determine when a reservoir within the chamber reaches maximum fluid capacity such sensor having a sending capability adapted to trigger an alarm and/or stop a remote or integral vacuum pump.
8. A chamber in accordance with any one of the preceding claims further including a vacuum leakage sensor adapted to warn against vacuum leakage to atmosphere.
9. A chamber in accordance with any one of the preceding claims including a collapsible transparent reservoir having an inlet port adapted to project through the second (inlet) port of the chamber in such a manner that the exterior surface of the reservoir inlet port releasably seals against the internal surface of the chamber inlet port.
10. A chamber in accordance with claim 9 hereof wherein the inlet port for the reservoir is of resiliently deformable silicon projecting from the reservoir and the inlet port of the chamber is a notch in the chamber adjacent its opening adapted to receive said silicon

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port and to sealingly captivate same when the opening in the chamber is in a closed state; the inlet port for the reservoir being adapted for releasable connection to tubing in order to facilitate communication with a wound site.

- 5 11. A chamber in accordance with claim 9 hereof wherein the inlet port for the reservoir extends into tubing terminating in a perforated cannula being adapted for insertion into living tissue.
- 10 12. A chamber in accordance with any one of claims 9 - 11 hereof wherein there are included means to positively locate the reservoir within the chamber.
- 15 13. A chamber in accordance with claim 12 hereof wherein the positive means comprise one or more hooks extending inwardly from an upper extremity of the chamber and adapted to pass through a corresponding hole in an upper extremity of the reservoir thereby suspending the reservoir within the chamber.
- 20 14. A chamber in accordance with claim 12 hereof wherein the positive means for locating the reservoir comprise one or more press studs on the interior of the chamber adjacent its upper extremity adapted to releasably lock onto a complementary press stud provided adjacent an upper extremity of the reservoir thereby suspending the reservoir within the chamber.
- 25 15. A collapsible reservoir for the containment of fluids

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adapted for use in conjunction with a chamber in
accordance with any one of the preceding claims wherein
there is included a magnet adjacent an upper portion of
the reservoir such magnet being adapted to trigger, vacuum,
cut out and/or alarm devices contained within a surrounding
chamber.

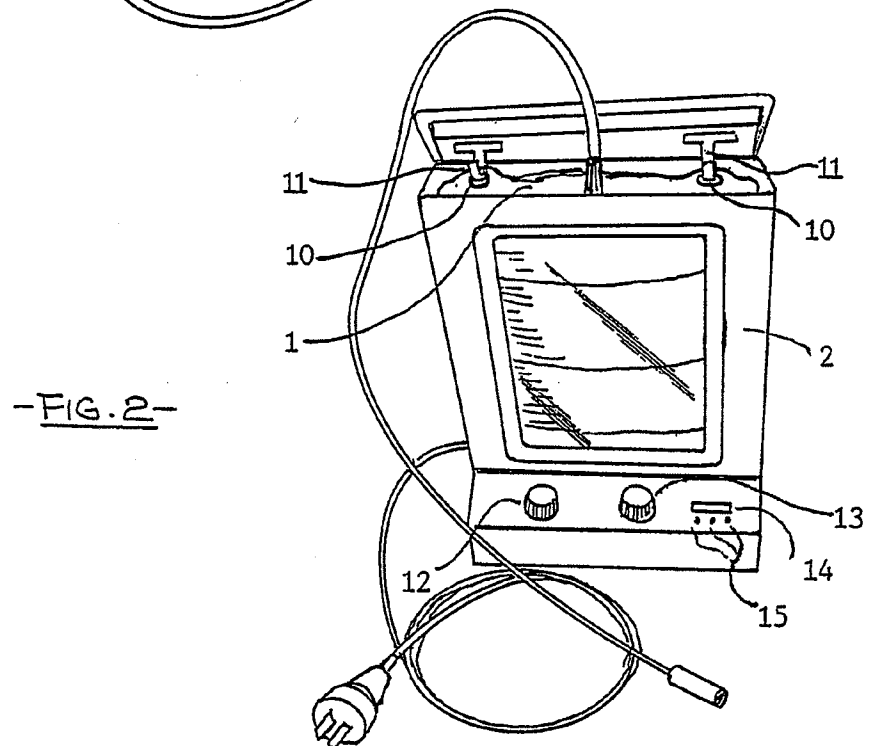
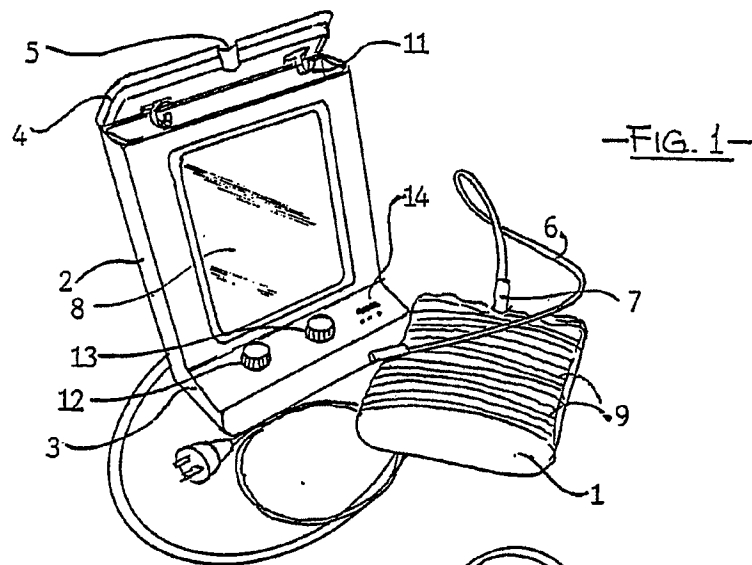
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16. A collapsible reservoir adapted for use in conjunction with a chamber in accordance with any one of the preceding claims such reservoir including two outwardly directed press studs on its external surface adjacent its upper extremity each press stud being in electrical communication with a conductive wire or strip extending to the interior of the reservoir adjacent its upper extremity in such a manner that when the reservoir fills the lower extremity of each of the respective strips or wires will contact the fluid in the reservoir.
17. A chamber substantially as hereinbefore described with reference to the accompanying drawings.
18. A reservoir substantially as hereinbefore described with reference to the accompanying drawings.



INTERNATIONAL SEARCH REPORT

International Application No PCT/AU 87/00024

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. ⁴ A61M 1/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC	A61M 1/00	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
AU : IPC as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X,Y	DE,A, 1810801 (GERHARD) 4 June 1970 (04.06.70)	(1,2,5,8)
X	DE,A, 2127764 (BOVERI & CIE) 30 November 1972 (30.11.72)	(1-3,5)
X	EP,A, 82510 (LAUTERJUNG) 29 June 1983 (29.06.83)	(1,8)
Y	US,A, 3713444 (BRIDGEMAN) 30 January 1973 (30.01.73)	(1,5,7,8)
X	US,A, 3685517 (REYNOLDS et al) 22 August 1972 (22.08.72)	(1,5)
X,Y	US,A, 4111204 (HESSEL) 5 September 1978 (05.09.78)	(1,5,7)
X	US,A, 4392860 (HUCK et al) 12 July 1983 (12.07.83)	(1,2,3)
X	US,A, 3782384 (TIMMERMANS) 1 January 1974 (01.01.74)	(1,2,5)
Y	US,A, 3556101 (ECONOMOU) 19 January 1971 (19.01.71)	(1,8)
X	GB,A, 1400139 (MATHYS) 16 July 1975 (16.07.75)	(1,3,5)
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IV. CERTIFICATION		
Date of the Actual Completion of the International Search		Date of Mailing of this International Search Report
27 April 1987 (27.04.87)		(05.05.87) 5 MAY 1987
International Searching Authority		Signature of Authorized Officer
Australian Patent Office		 R. HALLETT

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON
INTERNATIONAL APPLICATION NO. PCT/AU 87/00024

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members			
DE	2127764	CH	531351		
EP	82510	DE	3150500	DK	5612/82
		US	4522623		JP 58109061
US	3713444	US	3773211	US	3804089
US	4392860	BE	881084	BR	8000188
		CH	634999	DE	3000322
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US	3782384	DE	2106631	FR	2078817
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		IT	994643	JP	49058686
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